

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

ERBE USA, INC.,

Plaintiff,

v.

BYRNE MEDICAL, INC.,

Defendant.

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Civ. Action No. 1:11-cv-01480-AT

**ERBE USA, INC.'S OPPOSITION TO BYRNE MEDICAL, INC.'S
MOTION TO DISMISS PLAINTIFF'S COMPLAINT**

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I. Introduction

Defendant Byrne Medical, Inc.’s (“Byrne”) Motion to Dismiss Plaintiff’s Complaint and accompanying Memorandum of Law in Support of its Motion to Dismiss Plaintiff’s Complaint (collectively “Motion”) are a desperate attempt to *avoid* being held liable for its unlawful false marking and false advertising, and having to acknowledge that its U.S. Patent No. 6,210,322 (“the ‘322 patent”) is invalid. In its Motion, Byrne contends that: 1) ERBE’s false marking and false advertising claims, *i.e.*, claims 1-4, do not satisfy the pleading requirements of Rule 9(b), 2) ERBE’s same false marking and false advertising claims are barred by a recent settlement and release between the parties, and 3) this Court lacks subject matter jurisdiction to determine the validity of the ‘322 patent, *i.e.*, claim 5, because there is no “case or controversy.”

For at least the following four reasons, Byrne’s contentions are baseless. First, since ERBE has alleged the requisite “who, what, when, where, and how” of its false marking claims, ERBE pled its false marking claims with the particularity required by Rule 9(b). Second, as the pleading requirements of Rule 8(a) – and not Rule 9(b) – apply to false advertising claims under the Lanham Act, ERBE’s false advertising claims are sufficiently detailed to state a claim upon which relief can be granted. Third, the Settlement Agreement and Mutual Release (“Settlement Agreement”) of a recent arbitration between the parties does not, and cannot, bar

the false marking and false advertising claims asserted by ERBE since those claims could not have been brought by ERBE in the Arbitration because they do not arise from or relate to the underlying Distribution Agreement. And fourth, this Court has proper subject matter jurisdiction over ERBE's declaratory judgment for invalidity claim because there is an actual controversy between the parties.

II. Byrne's Arguments Are Insufficient to Support Dismissal of ERBE's Complaint

Byrne's Motion is actually two motions. Byrne seeks to dismiss ERBE's false marking and false advertising claims pursuant to Rule 12(b)(6), while it seeks to dismiss ERBE's declaratory judgment action pursuant to Rule 12(b)(1).

Byrne's Rule 12(b)(6) motion requires this Court to decide whether ERBE has set forth claims upon which this Court may grant relief. In considering Byrne's Motion, this Court must accept ERBE's allegations as true, *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984), and construe ERBE's Complaint in its favor. *Duke v. Cleland*, 5 F.3d 1399, 1402 (11th Cir. 1993) (citing *Linder v. Portocarrero*, 963 F.2d 332, 334 (11th Cir. 1992)). In recognizing the liberal rules as to the sufficiency of a complaint, the Eleventh Circuit has stated that it is a rare case in which a motion to dismiss should be granted. *See St. Joseph's Hosp., Inc. v. Hosp. Corp. of Am.*, 795 F.2d 948, 953 (11th Cir. 1986) (vacating the district court's granting of a motion to dismiss).

Similarly, when considering facial attacks¹ to subject matter jurisdiction under Rule 12(b)(1), as here, this Court must take the allegations in ERBE's Complaint as true. *See, e.g., Lawrence v. Dunbar*, 919 F.2d 1525, 1529 (11th Cir. 1990) (citing *Menchaca*, 613 F.2d at 511). Then, after accepting ERBE's allegations as true, this Court must determine whether ERBE's allegations are so patently without merit that it justifies this Court's dismissal for want of jurisdiction. *Simanonok v. Simanonok*, 787 F.2d 1517, 1519 (11th Cir. 1986). Based on this standard, "it is extremely difficult to dismiss a claim for lack of subject matter jurisdiction." *Id.*; *see also Garcia v. Copenhaver, Bell & Assocs., M.D.'s, P.A.*, 104 F.3d 1256, 1260 (11th Cir. 1997).

Hence, this Court should only grant Byrne's Motion, whether pursuant to Rule 12(b)(6) or 12(b)(1), if Byrne has demonstrated "beyond doubt that [ERBE] can prove no set of facts in support of [its] claim which would entitle [it] to relief." *Levine v. World Fin. Network Nat'l Bank, Structure, Inc.*, 437 F.3d 1118, 1120

¹ "Facial attacks" on a complaint "require[] the court merely to look and see if [the] plaintiff has sufficiently alleged a basis of subject matter jurisdiction, and the allegations in his complaint are taken as true for the purposes of the motion," whereas "factual attacks," challenge "the existence of subject matter jurisdiction in fact, irrespective of the pleadings, and matters outside the pleadings, such as testimony and affidavits, are considered." *Menchaca v. Chrysler Credit Corp.*, 613 F.2d 507, 511 (5th Cir. 1980), *cert. denied*, 449 U.S. 953 (1980) (citing *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977)). On a facial attack, a plaintiff is afforded safeguards similar to those provided in opposing a Rule 12(b)(6) motion -- the court must consider the allegations of the complaint to be true. *Williamson v. Tucker*, 645 F.2d 404, 412 (5th Cir. 1981), *cert. denied*, 454 U.S. 897 (1981).

(11th Cir. 2006) (citing *Harper v. Blockbuster Entm't Corp.*, 139 F.3d 1385, 1387 (11th Cir. 1998)) (emphasis added).

III. ERBE Pled its False Marking Claims with the Particularity Required by Rule 9(b)

As to the sufficiency of ERBE's pleading of its false marking claims, *i.e.*, claims 1 and 3 of ERBE's Complaint, Byrne makes but one misguided argument – that ERBE has not sufficiently alleged an “intent” element for its false marking claims. Byrne contends that in the Complaint, “there are no specific allegations of any facts which would suggest Byrne intended to deceive the public by its product labeling of EndoGator and SmartCap products” (D.I. 8-1 at 6), and thus ERBE's Complaint cannot satisfy Rule 9(b). Byrne's argument, however, is without merit. As Byrne correctly noted, a false marking claim includes an “intent to deceive” element, and a plaintiff needs to plead such a claim with sufficient specificity to meet the heightened pleading requirements of Rule 9(b). *Stauffer v. Brooks Bros., Inc.*, 619 F.3d 1321, 1328 (Fed. Cir. 2010). Here, ERBE's “intent to deceive” allegations sufficiently satisfy the particularity required by Rule 9(b).

A. ERBE does not have to allege “Intent” with particularity

As Rule 9(b) itself makes clear, while a plaintiff must “state with particularity” the “circumstances constituting fraud,” “[m]alice, intent, knowledge, and other conditions of a person's mind” may be alleged generally. Fed. R. Civ. P. 9(b). Thus, to satisfy Rule 9(b), ERBE must only allege with particularity the

“circumstances constituting fraud.” Here, the fraud is the false marking, so ERBE must only allege “the who, what, when, where, and how” of the alleged false marking. *Plasticos Vandux de Colombia, S.A. v. Robanda Intl.*, No. 10-60188-Civ, 2010 WL 5392646, at *1 (S.D. Fla. Dec. 21, 2010) (citing *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009)).

B. Since ERBE has alleged the requisite “who, what, when, where, and how”, it has sufficiently pled its false marking claims

From the Complaint, it is clear that ERBE has told Byrne exactly what the fraud entails, *i.e.*, the who, what, where, when and how of the alleged false marking. The Complaint tells: who committed the false marking, (Byrne,² as alleged throughout the Complaint (D.I. 1 at ¶¶ 14-15, 35-38, 42-46, 55-59)); what products are falsely marked (Byrne’s SmartCap and EndoGator products (D.I. 1 at ¶¶ 9-15, 18-19, 21, 30-38, 41-45, 54-58)) and what patent was falsely marked on the products and product advertisements (the ‘322 patent (D.I. 1 at ¶¶ 13-15, 18, 21, 24-29, 32, 34-38, 41-43, 54-56)); when the false marking occurred (from as early as the beginning of ERBE and Byrne’s business relationship until at least the date of the Complaint (D.I. 1 at ¶¶ 13-15, 18, 21)); where the false marking occurred (on the boxes in which Byrne shipped its SmartCap and EndoGator

² The identity of the particular individuals at Byrne involved in the false marking will become known to ERBE through the discovery process. *United States ex rel. Kennedy v. Aventis Pharm., Inc.*, 512 F.Supp.2d 1158, 1167 (N.D. Ill. 2007) (“It is well established [that] the requirements of Rule 9(b) are relaxed when the plaintiff lacks access to all facts necessary to detail his claim.”)

products, on distributed advertisements, and on Byrne's website (D.I. 1 at ¶¶ 13-15, 21)); and how the false marking was carried out (by placing the '322 patent number on the boxes in which Byrne shipped its SmartCap and EndoGator products, on advertisements of the accused products, and on Byrne's website (D.I. 1 at ¶¶ 13-15, 18)). By answering the five "who, what, when, where, and how" questions, ERBE has sufficiently pled its claims with particularity consistent with Rule 9(b).

The Complaint fully put Byrne on notice of the "circumstances" constituting Byrne's false marking, and contrary to Byrne's suggestion, ERBE cannot be expected to know, and therefore allege, all of the specifics regarding Byrne's false marking prior to obtaining discovery from Byrne. These specifics are solely in Byrne's possession and control, and can only be inferred from Byrne's actions.

Byrne contends that ERBE's "Complaint simply alleges that Byrne 'knew or should have known' that the '322 patent did not cover its EndoGator or SmartCap products" and cites to paragraphs 37, 38, 43, 44, 56 and 57 of the Complaint. D.I. 8-1 at 6. However, by citing only conclusory paragraphs of the Complaint, Byrne ignores and hopes this Court will ignore, the plethora of information regarding Byrne's false marking contained in paragraphs 8-36, 41, 42, 45-46, 54-55, 58 and 59, as noted above. Byrne half-heartedly attempts to buttress

its superficial contention by asserting that Byrne did not have the requisite intent to deceive:

The Complaint contains no allegations regarding who made a determination regarding patent coverage, or even that such a determination was ever made, or if so, when. The Complaint does not explain how someone intended the marking to deceive the public, or who had that intent and made that decision.

D.I. 8-1 at 6-7.

Contrary to Byrne's argument, ERBE sufficiently alleges an intent by Byrne to deceive. The Complaint tells a vivid story of Byrne's misleading of the public through falsely marking its products with the number of an irrelevant patent in order to gain a competitive advantage.³ See D.I. 1 at ¶¶ 13-21, 30-38, 40-46, 53-59. And, in this Court, false marking a product with a patent number to gain competitive advantage is evidence of an intent to deceive. For example, in denying a defendant's summary judgment motion in *Mohawk Indus., Inc. v. Interface, Inc.* – a case cited by Byrne in its Motion – this Court held that the defendant's attempt to use its patent “as a way to gain traction in the competitive carpet business” could

³ As the Federal Circuit has observed, “Congress intended the public to rely on marking as a ‘ready means of discerning the status of intellectual property embodied in an article of manufacture or design.’” *Clontech Labs., Inc. v. Invitrogen Corp.*, 406 F.3d 1347, 1356 (Fed. Cir. 2005) (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162, (1989)). Acts of false marking deter innovation and stifle competition in the marketplace. 7 Donald S. Chisum, *Chisum on Patents* § 20.03[7][c][vii] (2009). If an article that is within the public domain is falsely marked, potential competitors may be dissuaded from entering the same market.

lead a reasonable jury to determine that the improper marking was part of an “overall scheme” to deceive the public. No. 4:07-CV-212-HLM, 2008 WL 5210418, at *8 (N.D. Ga. Nov. 6, 2008). Consequently, the Complaint clearly alleges that Byrne deliberately intended to deceive the public into believing that its products were protected by patents, thereby causing ERBE and third parties to avoid developing competing products. *Robanda Int’l.*, 2010 WL 5392646, at *1-2.

Of course, Byrne is not estopped from asserting that it did not have the requisite intent to deceive. However, that factual dispute regarding whether Byrne’s intent rises to the level of statutory deception is a question of fact. *Clontech Labs., Inc.*, 406 F.3d at 1353 (citing *KangaROOS U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1573 (Fed. Cir. 1985)). Since ERBE has sufficiently pled its false marking allegations, there is a “rebuttable presumption” that Byrne falsely marked its product with a patent that does not cover the product for the purpose of deceiving the public. *See Pequignot v. Solo Cup Co.*, 608 F.3d 1356, 1362-63 (Fed. Cir. 2010). Byrne may rebut that presumption by gathering evidence during discovery and submitting that evidence to this Court.⁴

⁴ Contrary to Byrne’s contention at D.I. 8-1 at 7, there are facts which would support an allegation of intent to deceive. Therefore, Byrne’s Motion cannot be granted since a motion to dismiss is not defeated when a complaint contains “sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, — U.S. —, —, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

IV. ERBE's False Advertising Claims are Sufficiently Detailed to Satisfy the Pleading Requirements

A. The pleading requirements of Rule 8(a) apply to false advertising claims

Byrne contends that ERBE's false advertising claims, *i.e.*, claims 2 and 4 of the Complaint, fail to satisfy the Rule 9(b) pleading requirements, and thus should be dismissed. However, contrary to Byrne's contention, the pleading requirements of Rule 8(a) – and not Rule 9(b) – apply to false advertising claims under the Lanham Act. *See e.g., Dow Corning Corp. v. Jie Xiao*, 2011 U.S. Dist. LEXIS 54619, at *26 n.2 (E.D. Mich. May 20, 2011); *Wellnx Life Scis., Inc. v. Iovate Health Scis. Research, Inc.*, 516 F.Supp.2d 270, 283 n.2 (S.D.N.Y. 2007) (internal citations omitted). Contrary to Byrne's suggestion, neither Byrne nor this Court may, on its own, shift the false advertising pleading standard from Rule 8(a) to Rule 9(b). *See Leatherman v. Tarrant Cnty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993) (noting that pleading standards “must be obtained by the process of amending the Federal Rules, and not by judicial interpretation”).

B. ERBE's false advertising claims are sufficiently pled under Rule 8(a)

Pursuant to Rule 8(a), a complaint must only include “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2)). The short and plain statement need only “give the defendant fair notice

of what the . . . claim is and the grounds upon which it rests.” *Twombly*, 550 U.S. at 555 (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Thus, ERBE’s false advertising claims only have to provide Byrne with “enough facts to state a claim to relief that is plausible on its face.” *Twombly*, 550 U.S. at 570.

Byrne argues that “Erbe has not alleged a false statement in a commercial advertisement.” D.I. 8-1 at 9.⁵ Clearly that is not true. At paragraphs 8-38 of the Complaint, ERBE sets forth detailed facts that give Byrne fair notice of the false advertising claim and the grounds upon which it rests. For example, paragraph 14 of the Complaint states that Byrne distributed at least one advertisement, included as Exhibit A to the Complaint, stating that the EndoGator product was protected by an existing U.S. patent application, and paragraph 21 of the Complaint states that Byrne’s website indicates that the SmartCap product is protected by the ‘322 patent, included as Exhibit C to the Complaint. Moreover, at paragraphs 24-38, the Complaint details why Byrne’s statements, both in its advertisement and on its website, are false. Since ERBE’s Complaint sufficiently alleges that Byrne made false representations in commercial advertisements by falsely representing that its EndoGator and SmartCap products were patented products, Byrne’s motion to dismiss the false advertising counts should be denied.

⁵ Again, Byrne tries to persuade this Court by presenting a single unsupported, superficial argument.

V. The Settlement Agreement and Mutual Release Does Not Cover the Claims in ERBE's Complaint

Byrne, relying on nothing more than attorney rhetoric and creative wordsmithing, argues that the false marking and false advertising claims are barred by the release contained in the Settlement Agreement between the parties. D.I. 8-1 at 11-17.⁶ Byrne's arguments are without merit since the release, agreed to as part of the Settlement Agreement, is not broad enough to bar ERBE's false marking and false advertising claims.

As set out in the Complaint, ERBE and Byrne agreed to the Distribution Agreement. D.I. 1 at ¶¶ 11-12. Pursuant to Section 11.07 of the Distribution Agreement, the parties agreed to arbitrate "any dispute or disagreement . . . relative to this Agreement." Therefore, in a Demand for Arbitration, the parties could only raise issues that related to the Distribution Agreement. ERBE and Byrne then settled the Arbitration and entered into the Settlement Agreement.

A settlement agreement is a contract and is subject to the traditional rules of contract interpretation. *Norfolk S. Corp. v. Chevron, U.S.A., Inc.*, 371 F.3d

⁶ Byrne's reliance on *James v. Tarpley* and *McKissick v. Aydelott*, D.I. 8-1 at 14-16, is misplaced because those cases are not factually analogous to the present case. In *James*, the plaintiff claimed that his later-discovered injuries were from the automobile accident that was the subject of the release. 73 S.E.2d 188, 189 (Ga. 1952), while in the present case, ERBE's claims have no relationship to the Distribution Agreement. The holding in *McKissick* does not apply because the issue in *McKissick* was whether the trial court erred in admitting the release as evidence at trial, not whether the release encompassed certain claims. 705 S.E.2d 897, 901 (Ga. Ct. App. 2011).

1285, 1290 (11th Cir. 2004) (citing *Monahan v. Comm'r*, 321 F.3d 1063, 1068 (11th Cir. 2003)). Therefore, where the plain meaning of the agreement is clear, the court cannot go beyond the four corners of the document in interpreting the agreement. *Id.* As part of the Settlement Agreement, the parties agreed to the mutual release of their respective claims and defined claims to mean:

- (a) All claims ERBE alleged or could have alleged against Byrne as of the Effective Date in the Arbitration; and
- (b) All claims Byrne alleged or could have alleged against ERBE as of the Effective Date in the Arbitration; and
- (c) All claims either Party alleged or could have alleged against each other arising from or relating to the Distribution Agreement and claims that either Party failed to perform as required or allowed under the Distribution Agreement; and
- (d) All claims that either Party is liable to the other Party as a result of any action any Party took (or failed to take) arising from or relating to the Distribution Agreement, or the prosecution and defense of the Arbitration.

D.I. 8-3 at ¶ 9 (emphasis added).⁷ By the plain meaning of the agreement⁸, ERBE only released Byrne from (1) claims from actions that ERBE took (or failed to take) that arose out of or related to the Distribution Agreement, or the prosecution of the Arbitration (subsection (d)), and/or (2) claims that ERBE alleged or could

⁷ While ERBE does not challenge Byrne's "undisputed" facts, these "undisputed" facts are irrelevant to Byrne's Motion and do not support Byrne's allegation that the release set out in the Settlement Agreement bars ERBE from bringing the false marking and false advertising claims.

⁸ Byrne, in its brief, states that only subparagraphs (a) and (d) are relevant to its motion to dismiss. D.I. 8-1 at 12.

have alleged against Byrne as of December 1, 2010 in the Arbitration (subsection (a)).

A. ERBE's false marking and false advertising claims do not arise out of or relate to the Distribution Agreement⁹

ERBE's false marking and false advertising claims do not constitute a "controversy or claim arising out of or relating to" the Distribution Agreement. The Distribution Agreement established a manufacturer/distributor relationship between Byrne and ERBE – Byrne was obligated to manufacture products and sell them to ERBE, and ERBE was obligated to purchase those products from Byrne for distribution to ERBE's customers. D.I. 8-2. ERBE's claims for false marking and false advertising are not in any way related to Byrne's obligation to manufacture and sell products to ERBE, or ERBE's obligation to purchase products from Byrne and sell them to ERBE's customers. Accordingly, none of ERBE's present claims were released because none of them arose from, or were related to, the Distribution Agreement (the first clause of subsection 9(d) of the Settlement Agreement).

⁹ Although in its Motion, Byrne does not allege that ERBE's claims arose out of, or relate to, the Distribution Agreement, ERBE includes this section in order to completely address the releases deemed relevant by Byrne.

B. ERBE's false marking and false advertising claims do not arise out of or relate to the prosecution of the Arbitration

Whether a party has agreed to arbitrate an issue is a matter of contract interpretation. *Telecom Italia, SPA v. Wholesale Telecom Corp.*, 248 F.3d 1109, 1114 (11th Cir. 2001) (citing *United Steelworkers of Am. v. Warrior & Gulf Navigation Co.*, 363 U.S. 574, 582 (1960)). While language in the Distribution Agreement's arbitration clause calls for arbitration of "any controversy or claim arising out of or relating to" the Distribution Agreement, which is broad language, it does not require or permit arbitration of any dispute between the parties or any claim by either party against the other. D.I. 8-2 at § 11.07; *Telecom Italia*, 248 F.3d at 1114 (citing *Brown v. ITT Consumer Fin. Corp.*, 211 F.3d 1217, 1221 (11th Cir. 2000)). In the Eleventh Circuit, a claim is subject to arbitration only if the claim in question was an immediate, foreseeable result of the performance of contractual duties. *Id.* at 1116. Here, the only claims that should be subject to arbitration are those that are the "immediate, foreseeable result of the performance of" Byrne's manufacturing and ERBE's purchasing obligations. *See Telecom Italia*, 248 F.3d at 1116.

Disputes do not arise out of a contract if they "are not related - with at least some directness - to performance of duties specified by the contract." *Id.* (finding that a claim did not arise out of or was not related to the contract because the alleged misconduct could have occurred without a contractual relationship).

Moreover, a dispute is not “an immediate, foreseeable result of the performance of the contractual duties’ and thus not within the scope of an arbitration clause within that contract,” if “the defendant ‘could have been’ engaged in the allegedly tortious actions even if it ‘had no contractual relationship with’ the plaintiff.” *Hemispherx Biopharma, Inc. v. Johannesburg Consol. Invs.*, 553 F.3d 1351, 1367 (11th Cir. 2008) (citing *Telecom Italia*, 248 F.3d at 1116). Because Byrne could have engaged in false marking and false advertising, even absent the Distribution Agreement, those claims are clearly not within the scope of the arbitration clause of the Distribution Agreement and thus could not have been pursued by ERBE in the Arbitration. Consequently, none of ERBE’s claims were released because they could have been alleged by ERBE as of the Effective Date in the Arbitration (*i.e.*, Section 9(a) of the Settlement Agreement); nor could ERBE have prosecuted these claims in the Arbitration (*i.e.*, subsection 9(d) of the Settlement Agreement).

C. ERBE’s knowledge of Byrne’s false marking and/or false advertising as of December 1, 2010 is irrelevant

Byrne argues that ERBE released its claims for false marking and false advertising because “when ERBE filed the arbitration proceeding, and when it agreed to the Release, all of the facts giving rise to Claims 1-4 were known by ERBE.” D.I. 8-1 at 17. But, as usual, Byrne cites no support for its allegation. A distributor in a beneficial manufacturer-distributor relationship, such as ERBE prior to June 30, 2010, has no incentive to find reasons to terminate that

relationship. Thus, ERBE did not discover and had no reason to discover that Byrne was falsely marking and falsely advertising its products.

Moreover, even if ERBE knew “all of the facts giving rise to Claims 1-4” when it filed the Demand for Arbitration, ERBE could not have alleged them in the Arbitration, since such claims were not a part of the underlying Distribution Agreement (see, *supra*, at V.A.). Instead, ERBE would have had to pursue those claims, as it now has, in a United States district court. Subsection 9(a) of the Settlement Agreement specifically limits the release to claims ERBE could have alleged as of December 1, 2010 (the Effective Date of the Settlement Agreement) in the Arbitration.

Apparently, Byrne seeks, through creative wordsmithing, to read out the phrase “in the Arbitration” from the release. Through such creative wordsmithing, Byrne would have this Court find that ERBE agreed to settle the Arbitration by releasing Byrne from claims that (1) it could not have brought in the Arbitration, (2) were unrelated to the Distribution Agreement and unknown to ERBE, and (3) that arose from unilateral actions of Byrne that were unrelated to the Arbitration. Clearly, this Court should dismiss Byrne’s argument regarding ERBE’s alleged knowledge of false marking and false advertising.

VI. ERBE's Complaint Presents an Actual Controversy Sufficient for Declaratory Judgment Subject Matter Jurisdiction

The fundamental inquiry in determining whether there is a controversy sufficient for declaratory judgment jurisdiction is “whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)); *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 879 (Fed. Cir. 2008). Courts should look to the unique facts regarding the controversy and the “entirety of the relationship” between the parties in determining whether jurisdiction exists. *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 556 F.3d 1294, 1298 (Fed. Cir. 2009). Here, based on the facts and the entirety of the relationship between ERBE and Byrne, an actual controversy exists to warrant this Court’s jurisdiction over the declaratory judgment count.

A declaratory judgment plaintiff is not required “to put itself at further risk by continuing to engage in the allegedly infringing activity before seeking a declaration of its rights.” *Sony Elecs. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1284 (Fed. Cir. 2007); *Alpharma, Inc. v. Purdue Pharma L.P.*, 634 F. Supp. 2d 626, 631 (W.D. Va. 2009) (finding a justiciable issue “because without a declaration of its rights, the plaintiff will continue to operate on legally uncertain

grounds”). Instead, the Federal Circuit recognizes that declaratory judgment jurisdiction is appropriate “where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do,” which is precisely the case here. *Sony Elecs.*, 497 F.3d at 1284 (quoting *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007)).¹⁰

From the time Byrne and ERBE entered into the Distribution Agreement until the filing of this Complaint, Byrne represented that its EndoGator product was manufactured according to the ‘322 patent (D.I. 1 at ¶¶ 13-15; Exhibit A, at 3), distributed advertisements indicating that it was seeking (or had) patent protection for its EndoGator product, and marked, and continues to mark, the boxes in which it ships its EndoGator products with the ‘322 patent number. D.I. 1 at ¶ 13-15; Exhibit A, at 3-4. In addition, Byrne’s website stated that its SmartCap product was also protected by the ‘322 patent. D.I. 1 at ¶ 21. Because of Byrne’s representations of the coverage of its ‘322 patent, Byrne maintained a competitive advantage.

¹⁰ For example, in *Alpharma*, the court found an actual controversy because plaintiff had identified the patents which it believed would impede the marketing and sale of its product and identified the product that was the subject of the potentially infringing activity. 634 F. Supp. 2d at 630-31 (noting that a threat of litigation was not necessary and stating that “[i]n fact, in *SanDisk*, the defendant told the plaintiff that it would *not* sue, and that did not eliminate the justiciable controversy”).

Byrne informed ERBE that it was terminating the Distribution Agreement on June 30, 2010. In order to stay competitive in the market (having no future source for its products), ERBE had to find a manufacturer of a tubing product that was competitive with Byrne's EndoGator product and needed to develop a product that was competitive with Byrne's SmartCap product. D.I. 1 at ¶¶ 20-23. Thus, to stay competitive, ERBE was forced into a situation of either pursuing arguably illegal behavior, *e.g.*, patent infringement, or abandoning that which it had the right to do, *e.g.*, the right to remain competitive in the market. In light of *Sony* and other Federal Circuit precedents, based on these facts, this Court has declaratory judgment jurisdiction.

In its Motion, Byrne argues that since it has never threatened to sue ERBE or ERBE's customers for patent infringement, and ERBE did not allege that it did in the Complaint (D.I. 8-1 at 19), there is no controversy. The facts belie this argument. ERBE felt threatened by Byrne in light of the soured business relationship between them.¹¹ Moreover, Byrne told ERBE it would sue competitors that came too close to its patents.¹² But even if Byrne's actions and

¹¹ Once Byrne announced it was terminating the Distribution Agreement, ERBE discovered that not only was Byrne selling ERBE products at prices not in accordance with the Distribution Agreement, but that it was selling products directly to ERBE's customers, again in violation of the Distribution Agreement. Exhibit A at 4.

¹² At a meeting in Byrne's offices on March 2, 2011, Don Byrne, President of Byrne Medical, Inc., told ERBE representatives that Byrne had put together a legal

pronouncements do not amount to a threat to ERBE to sue for patent infringement, the Federal Circuit, in its post-*MedImmune* decisions, clearly articulated that in patent cases, a declaratory judgment plaintiff need not establish a reasonable apprehension of a lawsuit in order to show that there is an actual controversy between the parties. *Sony Elecs.* 497 F.3d at 1284.¹³

Byrne also argues that “[t]he mere fact that ERBE is introducing a product called CLEVERCAP, to compete with Byrne’s SMARTCAP product, is not enough.” D.I. 8-1 at 20. Again, Byrne’s argument fails in light of the Federal Circuit precedent which holds that a declaratory judgment plaintiff such as ERBE does not have to actually manufacture or sell potentially infringing products in order to qualify for declaratory judgment relief. *Cat Tech LLC*, 528 F.3d at 881.

In this case, similar to the plaintiff in *Cat Tech*, ERBE has clearly taken the requisite meaningful preparation to create its CleverCap product. ERBE has completed development of the CleverCap product (D.I. 1 at ¶ 22), formally introduced the product to the industry in May 2011, is currently offering the CleverCap product for sale, and will begin shipping its CleverCap product to

fund and set up offices for a lawyer and a legal assistant so that it could aggressively defend its IP. At that same meeting, Mr. Byrne further stated that U.S. Endoscopy’s tubing set (another competitor’s product) was very close to his patents. The specifics of Byrne’s threats will be revealed through discovery.

¹³ Byrne also argues that it “is not a highly litigious party” and that “[i]t has never sued anyone for patent infringement.” D.I. 8-1 at 19.

customers within weeks. *Id.* at ¶ 23. Since Byrne and ERBE are now direct competitors (*see Id.* at ¶¶ 20-23), this Court has declaratory judgment jurisdiction.

Byrne concludes its brief by stating that “[t]he totality of the circumstances make clear . . . that there is no case or controversy that would give rise to subject matter jurisdiction.” D.I. 8-1 at 20. As set forth above, Byrne’s conclusion ignores most of the facts in the Complaint, and ignores Byrne’s anti-competitive behavior vis-à-vis ERBE as set forth in the Demand for Arbitration. It was Byrne’s actions, in violation of the Distribution Agreement, that destroyed the business relationship between the parties and caused the substantial controversy between them. Moreover, now that Byrne and ERBE are direct competitors, and in light of Byrne’s misrepresentations about the scope of its ‘322 patent, clearly the parties have adverse legal interests.

Thus, considering all the circumstances, there is an actual controversy between Byrne and ERBE, sufficient to warrant a declaratory judgment of invalidity of the ‘322 patent.

VII. CONCLUSION

For all the foregoing reasons, Byrne's Motion should be denied.

Respectfully submitted,

Dated: June 17, 2011

By /s/ Christine S. Tenley

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FONT CERTIFICATION

I hereby certify that ERBE USA, INC.'s OPPOSITION TO BYRNE MEDICAL, INC.'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT is presented in Times New Roman 14 point font.

/s/ Christine S. Tenley
Christine S. Tenley

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

ERBE USA, INC.,

Plaintiff,

v.

BYRNE MEDICAL, INC.,

Defendant.

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Civ. Action No. 1:11-cv-01480-AT

CERTIFICATE OF SERVICE

This is to certify that on this 17th day of June, 2011, I electronically filed ERBE USA, INC.'S OPPOSITION TO BYRNE MEDICAL, INC.'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to the following attorneys of record:

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